K023259
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Helix Medical, Inc.
510(k) Summary
InHealth Soft Sleeve Colonoscope Splint

DEC 2 6 2002

I. NAME OF SUBMITTER

InHealth Technologies, a business unit of
Helix Medical, Inc.
1110 Mark Ave.
Carpinteria, Ca 93013

Establishment Registration Number: 2025182

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name: InHealth Soft Sleeve Colonoscope Splint
Common or Usual Name: Colonoscope Splint

Class II; 21 CFR 876.1500

The Soft Sleeve Colonoscope Splint is classified as 'Endoscope and Accessories'. The classification reads "An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices." The product code for this device is FDF, Colonoscope, Gastro-Urology.

III. PREDICATE DEVICES

- Olympus Splinting Tube, Olympus America, Inc., Melville, NY; K954451
- Pentax Splinting Tube, Pentax Precision Inst., Orangeburg, NY; K# Unknown
- ACMI Splinting Tube, AMCI Corporation, Houston, TX; K# Unknown

IV. DESCRIPTION

The InHealth Soft Sleeve Colonoscope Splint is a disposable splint or overtube for use in colonoscopy to prevent the reformation of the sigmoid loop subsequent to the reduction of the curvature of the sigmoid colon by the colonoscope during the colonoscopy procedure. This device is a silicone tube with a soft distal tip and a proximal grip. The distal tip provides a soft, conforming and flexible tapered shape that hugs the scope and facilitates insertion. The entire splint, with the exception of

the outer surface of the proximal grip, is coated with a lubricious, hydrophilic coating. This lubricious coating, when wetted, enables a smooth passage of the device along the colonoscope and of the splint through the sigmoid colon. The proximal grip is fitted with an injection port for injecting water into the inside of the splint tube to facilitate lubrication. The tip is grooved to allow flow of water from the inside diameter of the splint to the outside diameter to provide a controlled lubrication of the splint, the colonoscope, and the surrounding mucosa. The proximal grip, which is larger than the shaft, ensures that the entire tube does not pass through the anus and enter the rectum. The Soft Sleeve Splint is a non-sterile disposable device, intended for one-time use only, not intended for reuse.

V. INTENDED USE

The InHealth Soft Sleeve Colonoscope Splint is indicated for use with a colonoscope to prevent the reformation of the sigmoid loop subsequent to the reduction of the curvature of the sigmoid colon by the colonoscope during the colonoscopy procedure. The InHealth Soft Sleeve Splint is intended to provide for easy advancement of the scope while avoiding damage to the colon.

VI. TECHNOLOGICAL CHARACTERISTICS

The Soft Sleeve Splint is intended for the same use as its predicate devices, Olympus Splinting Tube, Pentax Splinting Tube, and the ACMI Splinting Tube. All these devices are indicated for use with a colonoscope to prevent the reformation of the sigmoid loop subsequent to the reduction of the curvature of the sigmoid colon by the colonoscope during the colonoscopy procedure.

The Olympus Splinting Tube is offered as a non-sterile product and is cleaned and disinfected between uses. As with the predicate devices, the InHealth Soft Sleeve Splint is intended for use in a non-sterile intact body orifice, and therefore is also provided non-sterile. The InHealth Soft Sleeve Splint is however, provided as a disposable device and therefore does not require any special cleaning. There is no reuse of this device.

The design, form, and materials of the Soft Sleeve Splint and its predicate devices are equivalent, in that all are designed to be a coated shaft through which the colonoscope is advanced during a colonoscopy. Helix Medical has introduced no new technology, or change in the intended use with the Soft Sleeve Splint. The Soft Sleeve Splint differs slightly in that it has a soft elastic distal tip rather than a rigid shaft.

The three predicate devices have a rubber or plastic type coating to provide a smooth splint surface. The Olympus requires an application of a lubricant to the splint prior to use. The InHealth Soft Sleeve Colonoscope Splint has a water

activated lubricious hydrophilic surface that provides a smooth splint surface as well as enabling easier passage of the colonoscope through the device and the device through the colon. The proximal grip is fitted with an injection port for injecting water into the inside of the splint tube to facilitate lubrication.

All four devices are designed for the colonoscope to pass through the splint. The three predicate devices are designed such that a gap remains between the colonoscope and the splint. The InHealth Soft Sleeve Colonoscope Splint is designed to provide a soft conforming shape that hugs the scope, thus minimizing the gap.

Helix Medical considers the use of the Soft Sleeve Splint to be substantially equivalent to its predicate devices, the Olympus Splint, Pentax Splint, and the ACMI Splint.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 6 2002

Ms. Cynthia M. Anderson
Vice President of Regulatory Affairs
and Quality Assurance
Helix Medical, Inc.
InHealth Technologies
1110 Mark Avenue
CARPINTERIA CA 93013

Re: K023259
Trade/Device Name: InHealth Soft Sleeve Colonoscope Splint (Model CS1200)
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FDF
Dated: September 30, 2002
Received: September 30, 2002

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023259

INDICATIONS FOR USE

Applicant: Helix Medical, Inc.

510(k) Number (if known): N/A*

Device Name: InHealth Soft Sleeve Colonoscope Splint

Indications For Use:

The InHealth Soft Sleeve Colonoscope Splint is indicated for use with a colonoscope to prevent the reformation of the sigmoid loop subsequent to the reduction of the curvature of the sigmoid colon by the colonoscope during the colonoscopy procedure. The InHealth Soft Sleeve Colonoscope Splint is intended to provide for easy advancement of the scope while avoiding damage to the colon.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023259

Prescription Use ✓ OR Over-the-Counter ____
Per 21 CFR 801.109